

**REMARKS**

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

**I. CLAIM STATUS & AMENDMENTS**

Claims 1-13 and 15-17 were pending in this application when last examined. Claims 2-12 have been withdrawn as non-elected subject matter.

Claims 1, 13 and 15-17 have been examined on the merits and stand rejected.

Claims 16 and 17 have been cancelled without prejudice or disclaimer thereto. Applicants reserve the right to file a continuation or divisional application on any cancelled subject matter.

Upon entry of the present amendment, claims 1-13 and 15 will be pending.

Claims 1, 13 and 15 have been amended.

Support for the amendment to claim 1, deleting the variant language, can be found in original claim 1 and in the specification, for example, at page 6, lines 27-35.

Support for the specific stringent conditions added to claims 13 and 15 can be found in the specification, for example, at page 6, lines 11-15.

Support for the term "isolated" added to claims 1 and 15 can be found in the specification, for example, at page 10, lines 24-26.

Claim 13 has been amended to effect minor corrections in punctuation.

Therefore, no new matter has been added by this amendment.

**II. EXAMINER INTERVIEW**

Applicants thank Examiner Steadman for the telephonic interview held October 19, 2004.

During the interview, it was clarified that claims 13 and 15 were rejected under 35 U.S.C. § 112, first paragraph, for a lack of enablement regarding the recitation of % homology language coupled with functional language, and not for a lack of written description.

**III. REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH**

Claims 13 and 15 have been newly rejected under 35 U.S.C. § 112, second paragraph, as indefinite regarding the “stringent conditions” for hybridization. See Office Action, item 13, pages 3 and 4.

It is respectfully submitted that the present amendment overcomes this rejection. Specifically, amended claims 13 and 15 now define the “stringent conditions” as described at lines 11-15 on page 6 of the specification.

Thus, the rejection of claims 13 and 15 under 35 U.S.C. § 112, second paragraph, is untenable and should be withdrawn.

**IV. REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH,  
WRITTEN DESCRIPTION**

Claims 1, 16 and 17 have been rejected under 35 U.S.C. § 112, first paragraph, for lacking written description support. See Office Action, items 14-15, pages 4-5.

It is respectfully submitted that the present amendment overcomes this rejection. Specifically, the variants language of claim 1 has been removed, and claims 16 and 17 have been cancelled.

Thus, the rejection of claims 1, 16 and 17 under 35 U.S.C. § 112, first paragraph, is untenable and should be withdrawn.

**V. REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH, ENABLEMENT**

Claims 1, 13 and 15-17 are rejected under 35 U.S.C. § 112, first paragraph, on the basis that the specification, while enabling for the protein of SEQ ID NO: 2 and a method for production thereof, is not enabling for any and all variants thereof. See Office Action, items 16-17, pages 6-7.

This rejection is respectfully traversed as applied to the amended claims for the following reasons.

Claim 1 has been amended to delete the “modifications selected from a substitution, a deletion, an addition, and an insertion” language. Thus, amended claim 1 is directed to the protein of SEQ ID NO: 2, which the Examiner indicated was enabled.

Claims 13 and 15 have been amended to delete the percent homology language and to recite the specific stringent hybridization conditions disclosed in the specification as suggested by the Examiner.

It is respectfully submitted that the specification enables the full scope of the amended claims.

As discussed in the previous response, the specification discloses proteins having PF1022 activity, and exemplifies the protein of SEQ ID NO: 2.

The specification, at page 6, lines 11-15, also discloses hybridization procedures under stringent conditions for isolating DNA that hybridizes with SEQ ID NO: 1 and which encodes the protein having the requisite activity. Moreover, routine procedures exist in the art for performing DNA hybridization reactions for identifying a sequence that hybridizes to another sequence under stringent conditions. Also, routine procedures exist for testing the protein encoded by the resultant DNA for the requisite biological activity as described at page 6, lines 21-27 of the specification.

Thus, using only routine experimentation, one skilled artisan could isolate DNA that hybridizes under stringent conditions to SEQ ID NO: 1 and use such DNA to produce a protein having the claimed cyclic depsipeptide synthetase activity. Certainly, such procedures do not amount to undue experimentation.

Therefore, the rejection of claims 1, 13 and 15-17 under 35 U.S.C. § 112, first paragraph, is untenable and should be withdrawn.

## **VI. REJECTION UNDER 35 U.S.C. § 102**

Claims 1 and 15 are again rejected under 35 U.S.C. §102(a), as anticipated by Weckwerth et al., A Journal of Biological Chemistry, vol. 275, No. 23, pp.17909-17915 (June 9, 2000). See Office Action, items 18-19, page 8.

This rejection is respectfully traversed as applied to the amended claims for the following reasons.

Attached herewith is a verified English translation of Japanese Patent Application No. 253040/1999, filed September 7, 1999, i.e., the priority document of the instant application. As can be seen, this Japanese Patent Application was filed prior to the publication date of June 9, 2000 of Weckwerth. Since the instant invention claims priority to this application and is fully supported therein, Weckwerth is no longer available as prior art against the claimed invention.

Thus, the rejection of claims 1 and 15 under 35 U.S.C. §102(a) is untenable and should be withdrawn.

## **VII. REJECTION UNDER 35 U.S.C. § 103**

Claim 13 is rejected under 35 U.S.C. §103(a), as obvious over Weckwerth in view of Leitner EP 0578616A2, Matsudaira, Methods Enzymol., vol. 182, pp. 602-613 (1990), Wozney, Methods Enzymol., vol. 182, pp. 738-751 (1990), and Aoyagi et al, U.S. Patent No. 5,763,221. See Office Action, items 21-22, pages 9-10.

This rejection is respectfully traversed as applied to the amended claims for the following reasons.

The rejection relied on Weckwerth for disclosing a PF1022 synthetase. However, as discussed above, Weckwerth is no longer available as prior art against the claimed invention.

Leitner neither discloses nor suggests the claimed PF1022 synthetase protein. Instead, Leitner discloses a cyclosporin synthetase, which is different from the claimed PF1022 synthetase.

Therefore, Leitner fails to disclose or suggest each and every element of the claimed invention, namely a protein having PF1022 synthetase activity.

The remaining references fail remedy the deficiencies of Weckwerth and Leitner, because they also fail to teach or suggest the PF1022 synthetase protein.

Therefore, the rejection of claim 13 under 35 U.S.C. §103(a) is untenable and should be withdrawn.

**CONCLUSION**

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance and early notice to that effect is hereby requested.

If it is determined that the application is not in condition for allowance, the Examiner is invited to telephone the undersigned attorney at the number below if he has any suggestions to expedite allowance.

Respectfully submitted,

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**ATTACHMENT TO AMENDMENT AND REPLY:**

1. Verified English translation of Japanese Patent Application No. 253040/1999, filed September 7, 1999, i.e., the priority document of the instant application.